K110189

JUL 18 2011

SECTION 5: 510(k) SUMMARY

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

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Date of preparation: January 21, 2011

Name of device:

Trade/Proprietary Name: Reprocessed Endoscopic Instruments

Classification Name: Electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic, reprocessed

Predicate Device	510(k) Title	Manufacturer
K012700	Vanguard Reprocessed Electrosurgical Instruments	Ascent Healthcare Solutions
K984240	ENDOPATH® Endoscopic Instruments	Ethicon Endo-Surgery, Inc.

Device description:

Endoscopic instruments consist of a rigid plastic handpiece with loop handles connected to the distal end scissors or jaws by an elongated, narrow-diameter insulated barrel or shaft. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula. The handpiece loop handles operate the jaws. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. The blades or jaws of endoscopic instruments can deliver a cauterizing current that enters the instrument through the unipolar cautery connector on the handpiece, runs down the insulated shaft and through the tissue in the blades or jaws. Monopolar electrocautery is possible only with instruments equipped with a cautery pin in conjunction with a compatible electrosurgical unit and patient grounding pad.

Note: Only the Endoscopic Instrument (5DCS) is the subject of this submission, the electrosurgical unit and any other related equipment are not included in the scope of this submission.

Indications for Use:	Scissor instruments are used during minimally invasive surgery in conjunction with an appropriately sized trocar and a compatible electrosurgical unit for mobilization, transection and/or cauterization of tissue.
Technological characteristics:	The design, materials, and intended use of Reprocessed Endoscopic Instruments are identical to the predicate devices. The mechanism of action of Endoscopic Instruments is identical to the predicate devices in that the same standard mechanical design and size and equivalent materials are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions' reprocessing of Endoscopic Instruments includes removal of adherent visible soil and decontamination. Each individual Endoscopic Instrument is tested for appropriate function of its components prior to packaging and labeling operations.
Performance data:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Endoscopic Instruments. This included the following tests: • Biocompatibility • Validation of reprocessing • Sterilization Validation • Function test(s) • Packaging Validation Performance testing demonstrates that Reprocessed Endoscopic Instruments perform as originally intended.
Conclusion:	Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Endoscopic Instruments) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ascent Healthcare Solutions
% Ms. Amanda Babcock
Senior Regulatory Affairs Specialist
10232 South 51st Street
Phoenix, Arizona 85044

JUL 18 2011

Re: K110189
Trade Name: Reprocessed Endoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: July 6, 2011
Received: July 7, 2011

Dear Ms. Babcock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110189

Device Name: Reprocessed Endoscopic Instruments

Indications For Use:
Scissor instruments are used during minimally invasive surgery in conjunction with an appropriately sized trocar and a compatible electrosurgical unit for mobilization, transection and/or cauterization of tissue.

The instrument, model 5DCS, is validated with the US Surgical Force FX-C generator and is only to be used with this generator.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110189

The only reprocessed model cleared in this submission is the Curved Scissor with Unipolar Cautery, Model 5DCS.

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110189